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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,445

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Ilan Tsafrir

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07/20/2009

MARTIN D. MOYNIHAN d/b/a PRTSI, INC.

P.O. BOX 16446

ARLINGTON, VA 22215

EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,445	<b>Applicant(s)</b> TSAFRIR ET AL.	
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 24, 25 and 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 26-34, and 40-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/2007</u> .                                               | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-44 are pending.

Claims 24, 25, and 35-39 are withdrawn

Claims 1-23, 26-34, and 40-44 are rejected.

### ***Election/Restrictions***

2. Applicant's election of the biological data species and the microarray or expression data subspecies in the reply filed on 09 June 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 24, 25, and 35-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 June 2009. It is noted that the restriction requirement mailed 18 May 2009 contained an error in indicating that the machine vision data species was claimed in claims 25 and 36-**69**, the machine vision data species is claimed in claims 25 and 36-**39**.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 25 September 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Drawings***

5. The color drawings were received on 29 January 2008. These drawings are accepted, and the petition to accept the drawings has been approved in the restriction requirement mailed 18 May 2009.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-23, 26-34, and 40-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-23, 26-34, and 40-44 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. The claims analyze data of a reordered distance matrix, but do not require the use of a computer or other device. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

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***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is indefinite for recitation of the phrase “intuitive easy to use GUI” because it is not clear what are the metes and bounds of intuitive and easy to use.

***Claim Rejections - 35 USC § 103***

10. For the purpose of examination the phrase “sorting points in neighborhoods” and the associated acronym SPIN has been interpreted to require comparison of continuous values of data that are not clustered into discrete groups, as discussed in the specification in the paragraph bridging pages 2-3.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-8, 20-22, 40, 42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skierczynski et al. (U.S. Patent No. 6,934,636 in view of Roberts (Pattern Recognition Vol. 30, pages 261-272 (1997)).

The claimed subject matter is a process of unsupervised analysis of a reordered distance matrix. In some embodiments the process produces a visualization of the data, the data is from a gene microarray, the data is presented in a graphical user interface, and an optional hierarchical cluster is produced. Because the limitation of claim 40 is optional, the limitation is not a required limitation of the claim.

Skierczynski et al. shows analysis of data by use of an ordered distance matrix in columns 3-4, 13, and 18. Skierczynski et al. shows a non-hierarchical clustering embodiment in columns 14 and 19-20. Skierczynski et al. shows generation of a hierarchical tree to show results in columns 13-14 and 20. Graphical results are presented in figures 1-17 and a computer apparatus that outputs results is shown in figures 18 and 19 and columns 6-8.

Skierczynski et al. does not show reordering a previously ordered distance matrix, or explicitly using an unsupervised analysis.

Roberts shows on pages 261-262 that hierarchical supervised clustering produces a dendrogram tree result, and that unsupervised clustering is an alternative clustering method that does not have an a priori number of partitions.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to reorder a distance matrix because Skierczynski et al. show ordering is

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applied to a distance matrix, and therefore Skierczynski et al. applies a new order to a previously unordered distance matrix. Regarding the limitation of an unsupervised analysis, Roberts shows that hierarchical clustering is known as supervised, and non-hierarchical clustering is known as unsupervised clustering. Skierczynski et al. therefore shows alternatives of using either supervised or unsupervised clustering methods because it shows use of either hierarchical or non-hierarchical clustering methods.

13. Claims 1, 23, 26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skierczynski et al. in view of Roberts as applied to claims 1-8, 20-22, 40, 42, and 44 above, and further in view of Golub et al. (Science Vol. 286, pages 531-537 (1999)).

The claimed subject matter is a process of unsupervised analysis of a reordered distance matrix. In some embodiments the data is of cancerous tissue, and the data is filtered and noise level is analyzed.

Skierczynski et al. in view of Roberts as applied to claims 1-8, 20-22, 40, 42, and 44 above do not show data of cancerous tissue or filtering of data and analysis of noise level.

Golub et al. shows in the abstract and throughout analysis of gene expression data of acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL), and clustering of the data is shown in figure 3. Golub et al. shows that the clustering analysis allows for ALL and AML to be distinguished by gene expression analysis in the abstract, and in figures 3 and 4. In footnote 15, Golub et al. shows quality control analysis of samples and exclusion of data if there is a low signal or aberrant signal images.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Skierczynski et al. in view of Roberts as applied to

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claims 1-8, 20-22, 40, 42, and 44 above by filtering aberrant data because Golub et al. shows that expression analysis of microarrays should have data removed if the signals are low or aberrant. It would have been further obvious to analyze samples of cancerous tissue because Golub et al. shows clustering analysis of leukemia cells is useful to distinguish between AML and ALL.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/  
Primary Examiner, Art Unit 1631

jsb